



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,080	10/24/2003	Thomas E. Kochy	A-70424/AJT	8476

7590 11/04/2004
Aldo J. Test
DORSEY & WHITNEY LLP
Suite 3400
4 Embarcadero Center
San Francisco, CA 94111

EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,080

Applicant(s)

KOCHY ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,9-12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,9-12 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/3/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1743

1. Claims 1-2, 5, 9-12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 9 of claim 1, the phrase “for said supporting said microwell plate or cuvette rack” does not make proper sense. On line 3 of claim 1, the phrase “in a rack” should be changed to – in a cuvette rack—since later in the claim, a cuvette rack is recited. On line 19 of claim 1, the phrase “adapted to receive said support tray and move the tray” is indefinite since it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. See *In re Hutchison*, 69 USPQ 138.

Claim 10 is indefinite since it depends from canceled claim 6.

On line 2 of claim 16, the phrase “said supporting tray” should be changed to –said support tray—so as to be consistent with the terminology used in claim 1.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kercso et al.

Kercso et al teach of a system for analyzing a large number of samples contained in standard multiwell plates or other array structures. In the system, multiwell plates 12 are moved on a conveyor to a test station 26 that includes a microfluidic device 40. An X-Y-Z robot arm 44 lifts a plate 12 from the conveyor and sequentially aligns the wells of the plate with a pipettor 46 extending downwardly from the microfluidic device 40. An optical detection system 48 optically monitors an analyzing volume in the channel network of the microfluidic device 40. The optical detection system acts as a cytometer as defined in instant claim 1 since it includes a suspended capillary that draws fluid past as analyzing region, wherein the sample is excited by light, and a fluorescence signal is detected and measured. See lines 36-41 and lines 65-67 in column 14 and lines 63-67 in column 15 of Kercso et al. The robotic arm 44 is able to move the plates in three dimensions. The arm lifts plates in the vertical or Z direction to transport the plates from the conveyor path 20 to the microfluidic device 40. This allows the microfluidic device to remain at a fixed location so that various optical and electrical components that interface with the microfluidic network do not have to be moved repeatedly. The robot arm positions a plate in the X-Y plane to sequentially align the wells of the plate with pipettor 46, thereby allowing the samples in the wells to be sequentially introduced into the channel network of the microfluidic device. Once the wells are aligned with the pipettor 46, the robotic arm can lift the plate to bring the sample in the aligned well into contact with the pipettor. The robotic arm 44 constrains a plate 12 by the use of a supporting tray or bracket 56 that fittingly engages

Art Unit: 1743

the plate so that the plate can be moved both laterally and vertically. See columns 3-4, column 9, lines 33-67, column 10, lines 1-2 and column 13, lines 25-51, and figures 1-4 in Kercso et al. Kercso et al teach that the X-Y-Z positioning system is commercially available from Parker-Hannifin Corporation as three independent linear actuators. See lines 46-50 in column 13 of Kercso et al. These linear actuators are comprised of motor driven lead screws, as evidenced by a brochure from Parker-Hannifin Corporation, cited herein. This brochure illustrates leadscrew drive mechanisms supported one by another for the repeatable positioning of objects or locations by horizontal, inverted or vertical translations. Therefore, the X-Y-Z positioning system taught by Kercso et al includes X-axis drive means, Y-axis drive means and Z-axis drive means each supported by the other and moveable in the X, Y and Z directions as recited in instant claim 1, and wherein the X-axis and Y-axis drive means comprise motor driven lead screws.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1743

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Gurgacz. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach that the Z-axis drive means comprises a motor driven cam.

Gurgacz teaches of a transfer mechanism for moving a support structure such as an arm 18 in an apparatus. The support arm 18 is moved horizontally or vertically in the apparatus by a motor driven cam 24 or 25. See lines 28-53 in column 3 of Gurgacz.

Based upon the combination of Kercso et al and Gurgacz, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the Z-axis drive means taught by Kercso et al as a motor driven cam since Gurgacz teaches that such means are conventional and useful in automatic devices to move a support structure in the horizontal and vertical directions.

8. Claims 5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Watts et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach of a mixing means associated with the pipettor 46.

Watts et al teach of an automatic chemistry analyzer 10 that comprises a sample probe arm assembly 80 as depicted in Figures 6a-6d. The sample probe arm assembly 80 includes a sample probe arm 82, a hollow sample probe 84 and a rotatable sample stirring rod 86 associated with the sample probe 84. The sample probe 84 is disposed generally vertically in the sample probe arm 82 and is movable by a sample probe motor 96 between a lower sample probe position and an upper sample probe position. The sample stirring rod 86 has a lower end 98, an upper end 100 and a stirring rod paddle 102. The sample stirring rod 86 is also disposed generally vertically in the sample probe arm 82 and is movable by a sample stirring rod motor 104 between

Art Unit: 1743

a lower sample stirring rod position and an upper sample stirring rod position. The sample stirring rod is also operatively rotated by a sample stirring rod rotating motor 105. The raising and lowering of the sample stirring rod is independent of the raising and lowering of the sample probe 84. The sample stirring rod 86 and the sample probe 84 are raised and lowered using a rack and pinion assembly 106. Therefore, Watts et al teach of a mixing means associated with a capillary or probe that can mix a sample in a container into which the mixing means is immersed by the raising and lowering of the mixing means and the rotation of the mixing means. See lines 19-65 in column 9 and figures 6a-6d of Watts et al.

Based upon a combination of Kercso et al and Watts et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to associate a mixing means adjacent to the pipettor 46 taught by Kercso et al that has the ability to move in the Z direction, similar to the sample stirring rod 86 taught by Watts et al, since Watts et al teach that it is beneficial to mix a sample held within an array of wells or rack before the withdrawal of the sample by a pipette or probe so that the sample is homogenous and all analytes or components within the sample are evenly distributed. It also would have been obvious to one of ordinary skill in the art to surround the pipettor 46 taught by Kercso et al with the mixing means taught by Watts et al rather than adjacent to the pipettor 46 since such an embodiment is merely an obvious engineering change in form or shape that allows the pipettor 46 to move in conjunction with the movement of the mixing means rather than being independent of the mixing means.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Nishi et al. For a teaching of Kercso et al, see previous paragraphs in this Office action.

Art Unit: 1743

Kercso et al fail to teach of a mixing means associated with the pipettor 46 that can vibrate the pipettor.

Nishi et al teach of a vibrating pipette probe mixer 10. A support 15 serves to move the pipette 10 to a series of different reaction vessels 8 for adding microliter quantities of solutions to each reaction vessel while simultaneously mixing the liquids therein. See lines 3-40 in column 2 and figures 1 and 3 in Nishi et al. Therefore, Nishi et al teach of a mixing means associated with a capillary or pipette that serves to vibrate the capillary/pipette.

Based upon the combination of Kercso et al and Nishi et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to associate a mixing means with the pipettor 46 taught by Kercso et al that has the ability to vibrate the pipettor in order to provide a mixing action, similar to the mixing means taught by Nishi et al, since Nishi et al teach that it is beneficial to mix a sample held within a reaction vessel before the withdrawal of the sample by a pipette or probe so that the sample is homogenous and all analytes or components within the sample are evenly distributed.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Hewett et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach that the multiwell plates 12 contain therein cleaning wells for selectively receiving and cleaning the pipettor 46.

Hewett et al teach of an automated liquid handling apparatus comprising a support bed 10 upon which a horizontally reciprocal table 12 is indexable selectively to bring a rack 14 of pipette tips 30 into alignment with a selectable row of wells 34 on a multiwell plate or into alignment with a trough 45, 46 or 47 on the table 12. The troughs can contain a reagent therein

Art Unit: 1743

or a wash liquid so that the pipette tips 30 can be brought into alignment with the wash troughs and washed between uses, thereby preventing one sample from contaminating another. Such washing allows the same tips to be used for a plurality of transfer steps without replacement or disposal of the tips. See lines 34-48 in column 3 and figure 1 of Hewett et al.

Based upon the combination of Kercso et al and Hewett et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the multiwell plates 12 taught by Kercso et al cleaning wells for selectively receiving and cleaning the pipettor 46, similar to the wash troughs 45, 46, or 47 in the apparatus of Hewett et al, since Hewett et al disclose that such cleaning wells or troughs in an automated liquid handling apparatus allow for the same pipette tips to be used for a plurality of liquid transfer steps without contaminating samples and without replacement or disposal of the tips.

11. Applicant's arguments filed August 20, 2004 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on April 30, 2004 have been withdrawn in view of Applicants' amendments to the claims. However, new rejections under this statute are set forth above.

Applicants are notified that the references on the Information Disclosure Statement filed on June 3, 2004 have been crossed out since these same references were already considered and made of record on the PTO-892 submitted with the Office action mailed on April 30, 2004.

Applicants argue the rejections of the claims under 35 USC 102 and 35 USC 103 based upon the primary reference to Kercso et al by stating that there is no teaching in this reference or in the secondary references of the particular arrangement of drive means now called for in

Art Unit: 1743

amended claim 1. In response to this argument, it is noted that the arrangement of drive means taught by Kercso et al is the same as recited in amended claim 1 since Kercso et al disclose that the X-Y-Z drive means are commercially available from Parker-Hannifin Corporation. The drive means are built from three independent linear actuators. See lines 47-51 in column 13 of Kercso et al. Upon reviewing the literature from Parker-Hannifin Corporation concerning robotic X-Y-Z positioning systems, it was found that these systems comprise linear actuators in the form of motor driven lead screws supported by one another for moving in the X, Y and Z directions. See the brochure cited herein from the Parker-Hannifin Corporation. Therefore, the teaching of Kercso et al that uses the technology disclosed in the Parker-Hannifin brochure encompasses the arrangement of drive means recited in claim 1.

For these reasons, Applicants' arguments are not found persuasive.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1743

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

November 2, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1000 1700